Arh. farm 2025; 75: S76 **PP 21**
https://doi.org/10.5937/arhfarm-61424

THE ROLE OF ARTIFICIAL INTELLIGENCE IN DRUG SAFETY

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Pharmacovigilance is a crucial component in ensuring the safety of drugs after they have been licensed and released to the public. Monitoring the adverse effects, interactions, and toxicity throughout the drug life cycle is essential. The World Health Organization defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. Artificial intelligence (AI) is increasingly applied in pharmacovigilance to manage large and heterogeneous datasets, predict adverse drug reactions (ADR/ADE), identify drug-drug interactions (DDI), and prioritize safety signals for timely intervention. Natural language processing (NLP) facilitates the extraction of ADR information from electronic health records (EHRs) and social media, thereby enhancing the sensitivity of surveillance systems [1]. Compared to traditional machine learning methods, deep neural networks and graph-based approaches demonstrate improved accuracy in predicting DDIs and ADRs. Outcomes depend on data quality and model architecture [2]. Novel techniques, such as federated learning and health-adapted language models, can help keep data private and scale up analysis; however, concerns remain regarding their transparency, reliability, and regulatory approval. Regulatory and international bodies call for standards, validation, and safeguards against bias and opacity before implementing large-scale pharmacovigilance processes [3]. While AI enhances the efficiency of signal detection and monitoring, proper practical integration requires multidisciplinary validation, reliable data oversight, and clear regulatory pathways to ensure that the benefits outweigh the risks.

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